#### REMARKS AND ARGUMENTS

#### Status of the claims

1) Examiner acknowledges previous amendments of claims 2, 5 and 15 and withdrawal of claims 9-14. Claims 1-3, 5-8 and 15-17 are currently pending. Claims 1-3, 6-8 and 15-17 are rejected in the current office action and claim 5 is objected to. Applicant cancels claims 3, 15 and 16; amends claims 1, 2, 5, 8 and 17.

## **Specification**

2) Examiner has withdrawn objection to the description for failure to include SEQ ID NO:'s after all amino acid sequences based on previously presented amendments.

## Claim objections

- 3) Examiner has withdrawn objection to claims 2 and 17 under 37 CFR 1.75 (c) based on previously presented amendments.
- 4) Examiner objects claims 3, 5 and 8 for failure to include a sequence identifier indicated by SEQ ID NO:s after amino acid sequences in the claims. In order to over come this objection Applicant has amended claims 5, and 8 so as to include a sequence identifier. Claim 3 is canceled.

#### Claim rejections under 35 USC section 112

- 5) Examiner sites 35 USC 112 second paragraphs: The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter with applicant regards as his invention.
- 6) Examiner has withdrawn rejection of claims 15-16 under 35 USC 112, second paragraph, in view of previously presented amendment of claim 15.

7) Claims 1-3,5-8, 15-17 are rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "corresponding to the structure of the active sites of the amino-terminal extension". Examiner states that it is not clear whether this limitation is intended to structurally limit the antimicrobial peptide by reciting its presence at the N-terminus or whether the intended structure of a sequence of the antimicrobial peptide is being correlated with the structure of the active-site of the amino-terminal extension. Therefore, Examiner deems claim 1 indefinite and claims 2-3, 5-8, 15-17 indefinite as being dependent of claim 1

Applicant has amended claim 1 by deleting the word 'structure' so as to over come this rejection. This language is supported for example on page 6 lines 30 -31 of the original specification, where it is stated that:"one can use as antimicrobials not all the sequence of the amino-terminal extension of subunit but a short peptide corresponding to the active site".

Applicant believes that this amendment makes the rejection moot and respectfully request reconsideration.

## Claim Rejections -35 USC section 102

3) Examiner sites 35 USC 102:

A person shall be entitled to a patent unless-

- b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country more than one year prior to the date of application for patent in the United States.
- 4) Claims 1-3, and 17 remain rejected under 35 USC 102 (b) as being anticipated by Hultgren et al. (USPN 6,001,823) for reasons set forth in previous office action.

The claims are drawn to an antimicrobial peptide comprising the sequence of Ala-Thr-Ala-Thr-Leu-Val represented by SEQ ID NO: 1.

In the reply to previous office action the Applicant argued that Hultgren et al discloses a sequence that comprises SEQ ID NO: 1 as inhibitors of pilus assembly located at the C-terminal of the pilus subunit. The Examiner states that Applicant submitted that the instantly claimed SEQ ID NO: 1 corresponds to the amino terminal end.

Examiner has considered the previous arguments without finding them persuasive. The Examiner states that to the extent that the Applicant defines the antimicrobial peptide comprising SEQ ID NO: 1 as corresponding to the structure of the amino-terminal extension of subunit assembly of adhesive organelle, the structure of the amino terminal extension of the subunit assembly is inherently encompassed by the sequence of the antimicrobial peptide. The teaching of Hultgren will inherently result in the claimed correspondence with the structure of an amino terminal extension of subunit assembly. Further, the Examiner respectfully submits that intended use of the antimicrobial peptide is not given patentable weight. Since the statements regarding preventing self-polymerization are indented use, they are not given any patentable weight.

Applicant reiterates what was stated in the previous reply: Hultgren discloses the binding motif between PapD and a peptide which constitutes the 19 amino acids of the C-terminal of a pilus subunit. According to the instant disclosure the peptide corresponds to the active cite of the amino terminal end. This means, that Hultgren discloses the C-terminal of a pilus subunit, while the antimicrobial peptide of the present invention corresponds to the active site of the amino terminal end. The short peptide according to this invention (SEQ ID NO: 1 consists of 6 amino acids only) consists of the active site of the amino terminal end of subunit and this is clearly a limitation of claim 1 as currently amended.

Moreover, Applicant has amended claim 1 language so as to indicate the prevention of self-polymerization as a characteristics of the peptide, and not as an intended use.

Therefore, the applicant is strongly of the opinion that the rejection should be withdrawn. Applicant respectfully request reconsideration.

Applicant has canceled claim 3 as being repetition of claim 5.

- 5) Examiner has withdrawn rejection of claim 5 as being anticipated by Wang L. et al. Applicant notes this with satisfaction.
- 6) Rejection of claims 6-8 under 35 USC 102(b) as being anticipated by Hochheimer et al. (Eur J. Biochem (1995) 234:910-920) has been withdrawn. Applicant notes this with satisfaction. However, upon further reconsideration a new ground of rejection is made in few of the reference of Macino et al (WO0032785).

The Examiner states that the claim is drawn to a peptide comprising the sequence of TTKL represented by SEQ ID NO: 4.

In the reply to the previous office action the Applicant argued that Hochheimer et al discloses a sequence that comprises SEQ ID NO: 4 only when the sequence of peptides 5 and 6 in the publication are read one after another. The Examiner found the argument persuasive. However, upon further consideration now the Examiner rejects claims 6-8 based on Macino disclosure. Macino et al disclose a sequence, with SEQ ID NO: 132 that comprises the sequence of SEQ ID NO:4, and align with the instant sequence at positions 9-12, thus meeting all the limitations of claims 6-8. The Examiner states that to the extent that the Applicant utilized the same sequence denoted by SEQ ID NO: 4 as was used by the teaching of Macino et al, the teaching of Macino et al would inherently result in the claimed properties of inhibiting polymerization of Dr. haemaglutinin.

Applicant respectfully request reconsideration of the new rejection based on the following:

Only claim 8 specifically refers to SEQ ID NO: 4. Claims 6 and 7 are applicable to any peptides that are according to claim 1. This is supported by the specification, for example page 11 lines 11-13, where it is stated that, peptide Ala-Thre-Ala-Thre-Leu-Val (SEQ ID NO:1) in the range of concentrations from 10<sup>-4</sup> to 10<sup>-8</sup> M clearly inhibits the expression of Caf1 on the surface cells. Therefore, the Applicant is of the opinion that the current rejection cannot apply to claims 6 and 7.

Moreover, the Applicant has carefully read through the publication of Macino et al. and does frankly not understand where the Examiner finds the sequence TTKL. The Examiner states that Macino discloses SEQ ID NO: 132 which comprise TTKL represented by SEQ ID NO: 4 in the current application. The applicant finds that Macino discloses three (3) sequences and there is no SEQ NO: 132. The applicant has carefully gone through the disclosed three sequences of Macino and cannot find the instant sequence. Therefore, the applicant cannot agree with this rejection and request reconsideration.

## Claim rejections -35 USC section 112

- 7) Examiner sites a quotation of the first paragraph of 35 USC section 112.
- 8) Claims 1-2, 6-7, and 15-17 are rejected under 35 USC section 112 first paragraphs, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed had possession of the claimed invention. The Examiner states that claims 1-2, 6-7 and 15-17 recite an antimicrobial peptide or inhibitor with unknown sequence that correlates to a tertiary structure of an active site formed from the assembly of surface organelle and intended use only. The Examiner states further, that as the genus of antimicrobial peptides, encompasses any random length, without any common sequence core and with any secondary structure, as long as it corresponds to the tertiary structure of the active site formed from the assembly of surface organelle also with unknown

structure, one skilled in the art would conclude that the disclosure of SEQ ID NO: 1, 4 and 5 is not representative of the undefined genus recited in the claims. Accordingly, the Examiner states that in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written.

Applicant wish to point out that the peptides are not of any random length, but they are short sequences corresponding to the active sites of the amino-terminal end of the extension of the subunits, and usually about 6 amino acid long as is stated on lines 28-30 of page 3 of the specification. Applicant has amended claim 1 and 2 by removing the word 'structure', whereby the applicant believes this rejection becomes moot as the claims peptides correspond to the active sites of the amino terminal sequence of the subunits.

Applicant has canceled claims 15 and 16 without prejudice.

# CONCLUSION

The applicant has replied to each objection and rejection made by the Examiner, either by amending the claims or by arguments. The applicant believes that the claims as now amended are allowable and therefore respectfully requests reconsideration of the rejections and allowance of the claims.

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